

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



**Antimicrobials Division (AD)**

April 02, 2013.

DP BARCODE: D407883.  
MRID: 48992101 & 48992102.  
SUBJECT: **Antimicrobial Corning Gorilla Glass.**  
REG. NO. OR FILE SYMBOL: 89661-R.  
DOCUMENT TYPE: Product Chemistry Review  
Manufacturing-use ☒ OR End - Use Product ☒  
INGREDIENT (PC Code) Silver Oxide (072500)

Ag+

CAS Number: 14701-21-4.  
TEST LAB: Technology Sciences Group Inc.  
SUBMITTER: Corning, Inc.  
GUIDELINE: 830 tables A & B.  
COMMODITIES: Formulation  
REVIEWER: Salvador Rodriguez.  
ORGANIZATION: AD.  
APPROVER: Karen P. Hicks.  
APPROVED DATE:

A handwritten signature is written over the date "04/03/13".

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**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

April 02, 2013.

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 89661-R.

**Product name:** Antimicrobial Corning Gorilla Glass.

**DP#:** 407883.

**From:** Salvador Rodriguez, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Marshall Swindell / Martha Terry.  
PM Team 33  
Antimicrobials Division (7510P)

**APPLICANT:** Wego Chemical & Mineral Corp.

**Action code:** A540.

**Due date:** 05/06/2013.

**Product Formulation  
Active Ingredient**

**% by wt**

Silver.....0.2

## BACKGROUND:

On behalf of the registrant, Corning Incorporated, the consultant, Technology Sciences Group Inc., has submitted a Confidential Statement of Formula (CSF), for the basic formulation and the OPPTS Guideline Series 830 Groups "A & B", to support the registration of the antimicrobial, integrated, non-food and end-use product **Antimicrobial Corning Gorilla Glass**. The product chemistry reviewer has reviewed the following documents:

- Transmittal letter, dated 11/13/12. MRID#: 48992100.
- Application for pesticide, dated 11/13/12.
- Confidential Statement of Formula, dated 11/13/12, for the basic formulation.
- Draft label, dated 11/13/12.
- OPPTS 830 Guideline tables A & B. MRID #'s: 48992101 & 48992102.
- Data matrix, dated 11/13/12.

## FINDINGS:

1. The CSF, dated 11/13/12, for the basic formulation is revised.
2. The CSF and the label do not have the same nominal concentration for the active ingredient (AI). The CSF shows a CAS number that is not in the Agency database for the AI. The name of the AI from the CSF differs from the 830 Group "A" guideline as well as the label. The AI name shown on the CSF is not in the Agency database as an active ingredient.
3. The CSF shows one inert ingredient. However, the 830 Group A guidelines, MRID # 48992101, shows several than one components that are not shown on the CSF.
4. All certified limits do not meet the EPA standard certified limits. Furthermore, the 830.1750 Certified Limits indicated that the inert ingredient is supposed to be under the EPA Standard Certified Limits. In addition, the active ingredient statement suggested that the certified limits are outside of the EPA Standard Certified Limits due to dependency of silver percentage content on the glass thicknesses. No data have been provided to support such claim.
5. The solid diluent/carrier agent shows nominal concentration. However, no purity is shown in column 10 of the CSF.
6. The OPPTS Guidelines Series 830 Groups "A & B" product chemistry data requirements applicable to end-use products have not been met. The data provided for this group "A & B", are not based on the silver oxide as active ingredient, it is based on the silver nitrate as an active ingredient (AI). MRID #: 48992101 & 48992102.

7. The name of the active ingredient and the nominal concentration on the label is different from the CSF.
8. The label does not provide information about where the silver metallic is coming from, since the silver is not coming as metal.

#### **CONCLUSIONS:**

Product Science Branch of Antimicrobials Division finds the proposed CSF for the basic formulation, dated 11/13/12, is not acceptable. The AI shown on the CSF is not in the Agency database. The OPPTS 830 Groups "A & B" guidelines are not acceptable since the CSF, label and the studies do not harmonize. The justification for wider certified limits are is not acceptable. The registrant must provide data that support the rationale. The product chemistry package is not acceptable. The storage stability and corrosion characteristic studies must be provided to the Agency.

#### **RECOMMENDATIONS:**

1. The proposed AI must be added to the Agency database as an AI, since this molecule is a new active ingredient.
2. The CSF, label, and the studies must harmonize.
3. The wider certified limits range must provide data that supports such claim.
4. The CSF must provide all components that are listed in OPPTS 830 Group "A" guidelines including trade names.
5. The registrant must not show the nominal concentration on the CSF for the inert ingredient. Since EPA does allow to show the nominal concentration of an inert ingredient.
6. Under the 40CFR 158.350 certified limits, the registrant must use a 3% window to calculate the certified limits of an inert ingredient concentration > 20% in order to meet the EPA Standard Certified Limits.

**Table A:**  
**Product Chemistry (Series 830, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	N	48992101
830.1600 Description of Materials	N	48992101
830.1620 Production Process <sup>2</sup>	N	48992101
830.1650 Formulation Process <sup>3</sup>	N	48992101
830.1670 Formation of Impurities <sup>4</sup>	N	48992101
830.1700 Preliminary Analysis <sup>5</sup>	N	
830.1750 Certified Limits <sup>6</sup>	N The certified limits are based on silver oxide. However, the label does not show the silver oxide.	48992101
830.1800 Enforcement Analytical Method <sup>7</sup>	N	48992101
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**  
**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	N		48992102
830.6303 Physical State	N		48992102
830.6304 Odor	N		48992102
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	<i>[Not required for end-use products.]</i>	
830.6314 Oxidation/Reduction; Chemical Incompatibility	N		48992102
830.6315 Flammability/Flame Extension	N		48992102
830.6316 Explodability	N		48992102
830.6317 Storage Stability	N		48992102
830.6319 Miscibility <sup>1</sup>	N		48992102
830.6320 Corrosion Characteristics	N		48992102
830.6321 Dielectric Breakdown Voltage	NR	<i>[Not required for end-use products.]</i>	
830.7000 pH <sup>2</sup>	N		48992102
830.7050 UV/Visible Absorption	NR	<i>[Not required for end-use products.]</i>	
830.7100 Viscosity	N		48992102
830.7200 Melting Point/Melting Range	NA	<i>[Not required for end-use products.]</i>	
830.7220 Boiling Point/Boiling Range	NA	<i>[Not required for end-use products.]</i>	
830.7300 Density/Relative Density/Bulk Density	N		487401-01
830.7370 Dissociation Constants in Water	NA	<i>[Not required for end-use products.]</i>	
830.7550/830.7560/830.7570 Partition Coefficient	NA	<i>[Not required for end-use products.]</i>	
830.7840/830.7860 Water Solubility	NA	<i>[Not required for end-use products.]</i>	
830.7950 Vapor Pressure	NA	<i>[Not required for end-use products.]</i>	

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